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K012170
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SOREDEX

510(k) Summary

Date
July 10, 2001

Submitters Information
Soredex Instrumentarium Corporation
Nilsiankatu 10 – 14
00510 Helsinki
Finland
Phone: +358 9 39371
Fax.: +358 9 7015261
Contact: Kai Lanér

Trade Name
Digora PCT

Common Name
Imaging plate reader

Classification
Solid state x-ray imager

Predicate Device
On physical performance:
Digora
510(k): K934949
On diagnostic performance:
Conventional film screen combination

Product Description
A digital radiography system for imaging plates located in cassettes. The system may be used with x-ray equipment utilizing film or similar cassettes. The image is recorded on reusable imaging plate which substitutes for conventional x-ray film. The x-ray energy absorbed in the imaging plate remains stored as a latent image. When fed to the device the stored energy is released as an optical emission proportional to the stored energy when the imaging plate is stimulated pixel by pixel by a scanning laser. An optical system collects the emission for photoelectronic system, which converts the emission to digital electronic signals. These signals are processed in a computer system which formats and stores the signals.

Further image processing, display and achieving are carried out with an auxiliary software (such as Digora for Windows K983267), a PC and a CRT.

Intended Use
The Digora PCT imaging system is indicated for capturing, digitization and processing of extraoral, maxillofacial and cephalometric x-ray images stored in imaging plate recording media.

Technological Characteristics
The subject device represents a change to the predicate device in form of reading larger imaging plates such as 15 cm x 30 cm, 18 cm x 24 cm and 24 cm x 30 cm or 8 inch x 10 inch and 10 inch x 12 inch. The image pixel bit depth in the predicate device is 8 bits and correspondingly in the subject device 16 bits.

Performance data
A comparison between Digora PCT and Digora was made to evaluate the need of dose to produce equal pixel value of a known object and the spatial resolution. The dose required to for a certain pixel-value was a ¼ of that required for Digora. Spatial resolution for Digora PCT is 4 lp/mm, and 6 lp/mm for Digora. Digora PCT was found to be substantially equivalent to Digora.
A comparison between Digora PCT and Kodak T-Mat G film/Lanex Regular intensifying screens was made to evaluate the ability of the device to provide images of equivalent diagnostic capability to those of a cleared predicate device. Digora PCT was found to be substantially equivalent to a film screen combination.

Conclusion
Digora PCT has found to have substantially equivalent physical performance as the predicate device Digora.
Digora PCT is shown to be able to provide images of equivalent diagnostic capability to those of a cleared film screen combination.
Digora PCT is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Kai Laner
Director
Soredex Instrumentarium Corporation
Nilsiankatu 10 - 14
HELSINKI FIN 00510
FINLAND

AUG 21 2013

Re: K012170
Trade/Device Name: Digora PCT (Imaging plate reader)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH, EHD, and MQB
Dated: July 10, 2001
Received: July 12, 2001

Dear Mr. Laner:

This letter corrects our substantially equivalent letter of August 10, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510 (k) NUMBER : K012170

DEVICE NAME : DIGORA PCT

INDICATIONS FOR USE :

The Digora PCT imaging system is indicated for capturing, digitization and processing of extraoral, maxillofacial and cephalometric x-ray images stored in imaging plate recording media.

Prescription Use ✓

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012170